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SUBJECT: FINNISH GOVERNMENT APPROVES PHARMACEUTICAL

REFERENCE PRICING SYSTEM

¶1. Summary: In a disappointing move and despite Embassy and industry efforts, the Finnish cabinet voted unanimously June 25 to approve a reference pricing scheme for pharmaceuticals, a provision of which undermines the value of patent protection for medicines created and manufactured by U.S. and other pharmaceutical companies. Parliament is expected to approve the proposal at the end of the summer. Despite the fact that the Ministry of Economy and Employment, the Ministry of Foreign Affairs and the Chancellor of Justice initially opposed the proposal and Prime Minister Vanhanen was equivocal, in the end all acquiesced and supported the Minister of Social Affairs and Health and the short-term attraction of an estimated 50 million euros annually in savings. Embassy will engage key parliamentary figures in the next month to urge that the government develop a revised proposal that achieves their stated objective of containing health care costs but that will maintain the level of intellectual property protection that pharmaceutical companies have previously enjoyed in Finland and continue to enjoy elsewhere in the European Union. If the proposal passes as written, post will consult with local U.S. industry and Washington to determine if a Special 301 listing is appropriate in the 2009 cycle. End Summary.

Background

¶2. Product patents have been granted in Finland only since ¶11995. As such, nearly all products on the Finnish market are still protected only by analogous process patents. Prior to 2006, when Finland enacted the fix it is now proposing to withdraw, the level of protection for innovative medicines in Finland was among the lowest in the EU. At that time, industry faced three major hurdles that taken together formed a perfect storm: weak patent protection, liberal market authorization and mandatory generic substitution.

Finland Does the Right Thing But Then Changes Course

¶3. After much Industry and Embassy lobbying, in 2006, the Finnish government established criteria in Section 57(c) of its Medicines Act that excluded pharmaceutical products from generic reimbursement if they were protected by an analogous process patent in Finland and enjoyed valid patent protection in at least five other countries in the European Union. 57(c) was the result of long negotiations and was seen by industry as a fair and equitable solution. Indeed, it was used as an example for other countries, notably Norway, of the ideal legislative remedy. Trouble started in the summer of 2007 when the Finnish Pharmaceutical Pricing Board (PPB) began cancelling the reimbursement status of some innovative drugs, claiming the PPB was bound only by the Health Insurance Act, not the the Medicines Act that contained the

exclusion criteria. At first, Industry and Econoff believed this was an isolated action by an overzealous PPB chief, especially because when we raised it with the newly-installed Health Minister, she freely admitted she did not know what we were talking about. Clearly she eventually got up to speed, because before long her ministry was overtly supporting the complete withdrawal of the 57(c) arrangement instead of supporting similar exclusion criteria for the Health Insurance Act as industry was proposing.

USG and Industry Efforts

¶4. Beginning late last year, Econoff and Commercial Officer began working closely with the U.S. pharmaceutical company representatives here in Finland as well as with the local trade association Pharma Industry Finland (PIF) and its director, former Finance Minister Suvi-Anne Siimes to devise a strategy to head off the cancellation of 57(c). Since January 2008 the Embassy has raised this at the highest level of Finnish government, including with the Prime Minister but also with virtually every other minister in the entire government. Our strategy, carefully coordinated with industry and Washington, has focused on underscoring that Finland's knowledge-based economy has attracted much r&d investment, including health-related project funds from the USG. A small IPR deficiency would undermine Finland's deserved reputation for innovation, a blow that was surely not worth the short-term gains from savings. Industry reinforced this message during the visit of Alex Azar, Eli Lilly's Senior VP for Corporate Affairs (and a former Deputy Secretary of HHS) and through intensive lobbying by PIF and Siimes. Siimes has also reached out to the German, French

and Swiss Embassies whose companies also stand to suffer under the new arrangement. USTR Ambassador Schwab and Secretary Gutierrez have written their Finnish counterparts on this issue and it has been raised with the Finnish Embassy in Washington and during the visits of high-level Finnish government officials.

Next Steps

¶5. With the cabinet's approval of the reference pricing scheme and the subsequent removal of the protection innovative products enjoyed under Section 57(c), there are few steps left. Nonetheless, Embassy has a small window until the end of the summer when parliament will reconvene and consider the proposal. Given that the MPs' party representatives in the cabinet have already approved the proposal, however, chances for success are slim. However, we remain committed to raising this with parliamentary leaders in an attempt to encourage the development of a revised proposal. If that fails, we will examine whether this unfortunate set of events merits Finland's inclusion on the Special 301 list.

BUTLER